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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,118	11/12/2003	Stephen C. Macevicz	55525-8045.US01	8171

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PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,118	MACEVICZ, STEPHEN C.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-33* is/are pending in the application.

4a) Of the above claim(s) *23-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/7/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on January 3, 2005 has been entered. The claims pending in this application are claims 23-33 wherein claims 23-27 have been withdrawn due to restriction requirement. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendments filed on January 3, 2004.

Claim Objections

2. Claim 28 is objected to because of the following informalities: "a single said restriction fragment" in lines 5 and 6 should be "one of said restriction fragments".

3. Claim 32 is objected to because of the following informalities: (1) "said plurality of oligonucleotides is" in lines 1 and 2 should be "said plurality of oligonucleotides are"; and (2) "each said restriction fragment" in lines 3 and 4 should be "each of said restriction fragments".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by New England Biolabs 96/97 Catalog (page 115).

Regarding claim 28, New England Biolabs 96/97 Catalog teaches a BamH I-Pst I adaptor and an EcoR I-Pst I adaptor (see page 115). Since both the BamH I-Pst I adaptor and the EcoR I-Pst I adaptor taught by New England Biolabs 96/97 Catalog is are 22 bases in length, this catalog discloses that a plurality of pairs of oligonucleotides (ie., the BamH I-Pst I adaptor and the EcoR I-Pst I adaptor), each containing a ligated pair of sequence tag (ie., 2 of nucleotide sequences with 11 bp in the BamH I-Pst I adaptor or the EcoR I-Pst I adaptor); wherein each said ligated pair of said sequence tags is from nine to eighteen basepairs in length as recited in claim 28. Although this catalog does not teach that each said ligated pair of said sequence tags consists of opposite end segments of one of said restriction fragments of said genomic DNA as recited in claim 28, since that claim 28 is directed to a product and is not directed to a method of making a product, the patentability of claim 28 does not depend on how the product recited in claim 28 is made. It is known that the patentability of a product does not depend on its method of production. If the claim is a product-by-process claim, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claims 29-31, since claims 29-31 are directed to a method for making the product of claim 28, claims 29-31 are anticipated by New England Biolabs 96/97 Catalog.

Regarding claim 32, New England Biolabs 96/97 Catalog teaches that said plurality of pairs of oligonucleotides are a sample (ie., a composition comprising a BamH I-Pst I adaptor and an EcoR I-Pst I adaptor) having a size (ie., 22 bp) sufficient to contain with a probability of ninety-nine percent at least one copy of each of said pairs of sequence tags (ie., 11 bp). Although this catalog does not teach that at least one copy of said pairs of sequence tags is from each said restriction fragment of said genomic DNA as recited in claim 32, since that claim 32 is directed to a product and is not directed to a method of making a product, the patentability of claim 32 does not depend on how the product recited in claim 32 is made. It is known that the patentability of a product does not depend on its method of production. If the claim is a product-by-process claim, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claim 33, New England Biolabs 96/97 Catalog teaches that each sequence tag of each of said pairs contains the same number of basepairs (ie., two 11 bp fragments in the BamH I-Pst I adaptor or the EcoR I-Pst I adaptor) as recited in claim 33.

Therefore, New England Biolabs 96/97 Catalog teaches all limitations recited in claims 28-33.

6. Claims 28-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Sapolsky *et al.*, (US Patent No. 5,710,000, published on January 20, 1998).

Sapolsky *et al.*, teach capturing sequences adjacent to type-IIs restriction sites for genomic library mapping.

Regarding claim 28, since Sapolsky *et al.*, teach a 266 bp fragment with an EarI site on one end of the fragment and a Hga I site on another end of the fragment (see column 5 and Figures 2 and 3), Sapolsky *et al.*, disclose that a plurality of pairs of oligonucleotides (ie., multiple identical fragments with 266 bp taught by Sapolsky *et al.*,), each containing a ligated pair of sequence tag (ie., a nucleotide sequence with 10 bp at one end of the fragment and a nucleotide sequence with 10 bp at another end of the fragment); wherein each said ligated pair of said sequence tags is from nine to eighteen basepairs in length as recited in claim 28. Although Sapolsky *et al.*, do not teach that each said ligated pair of said sequence tags consists of opposite end segments of one of said restriction fragment of said genomic DNA as recited in claim 28, since that claim 28 is directed to a product and is not directed to a method of making a product, the patentability of claim 28 does not depend on how the product recited in claim 28 is made. It is known that the patentability of a product does not depend on its method of production. If the claim is a product-by-process claim, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claims 29-31, since claims 29-31 are directed to a method for making the product of claim 28, claims 29-31 are anticipated by Sapolsky *et al.*.

Regarding claim 32, Sapolsky *et al.*, teach that said plurality of pairs of oligonucleotides are a sample (ie., multiple identical 266 bp fragments with an EarI site on one end of the fragments and a Hga I site on another end of the fragments taught by Sapolsky *et al.*,) having a size (ie., 266 bp) sufficient to contain with a probability of ninety-nine percent at least one copy of each of said pairs of sequence tags (ie., 10 bp). Although Sapolsky *et al.*, do not teach that at least one copy of said pairs of sequence tags is from each said restriction fragment of said genomic DNA as recited in claim 32, since that claim 32 is directed to a product and is not directed to a method of making a product, the patentability of claim 32 does not depend on how the product recited in claim 32 is made. It is known that the patentability of a product does not depend on its method of production. If the claim is a product-by-process claim, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claim 33, Sapolsky *et al.*, teach that each sequence tag of each of said pairs contains the same number of basepairs (ie., two 10 bp nucleotide sequences in the fragments taught by Sapolsky *et al.*,) as recited in claim 33.

Therefore, Sapolsky *et al.*, teach all limitations recited in claims 28-33.

Response to Arguments

In page 6, third paragraph bridging to page 7, first paragraph of applicant's remarks, applicant argues that "two recognition sites on opposite ends of an intact restriction fragment of DNA, as described in Sapolsky *et al.*, cannot be considered 'a ligated pair of sequencing tag...from nine to eighteen basepairs in length'. ".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Since Sapolsky *et al.*, teach a 266 bp fragment with an EarI site on one end of the fragment and a Hga I site on another end of the fragment (see column 5 and Figures 2 and 3), and a 10 bp nucleotide sequences on one end of the fragment is connected to another 10 bp nucleotide sequences on another end of the fragment in the fragments, and the claims do not require that the pair of sequence tags directly connects each other, Sapolsky *et al.*, teach the oligoncleotide containing a ligated pair of sequence tags.

7. Claims 28-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgante *et al.*, (WO 96/17082, published on June 6, 1996)

Regarding claim 28, since Morgante *et al.*, teach that the restriction enzymes with 4-, 5-, 6- , or 8-bp recognition site such as Taq I, Pst I and Hind III (see page 75, first paragraph) are combined to generate genomic DNA restriction fragments (see page 30) and ligate synthetic oligonucleotide adaptors (tag) with approximately 10-30 bp long (page 51, first paragraph) to the ends of genomic DNA restriction fragments in order to form ligated products (page 50, third paragraph and Figure 1a), Morgante *et al.*, disclose that a plurality of oligonucleotides (ie., the ligated products), each containing a ligated pairs of sequence tags (ie., two 10 bp adaptors on

ends of the ligated products), wherein each said ligated pair of sequence tags is from nine to eighteen basepairs in length as recited in claim 28. Although Morgante *et al.,* do not teach that each said ligated pair of said sequence tags consists of opposite end segments of one of said restriction fragment of said genomic DNA as recited in claim 28, since that claim 28 is directed to a product and is not directed to a method of making a product, the patentability of claim 28 does not depend on how the product recited in claim 28 is made. It is known that the patentability of a product does not depend on its method of production. If the claim is a product-by-process claim, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claims 29-31, since claims 29-31 are directed to a method for making the product of claim 28, claims 29-31 are anticipated by Morgante *et al.*.

Regarding claim 32, Morgante *et al.,* teaches that said plurality of pairs of oligonucleotides are a sample (ie., a sample having the ligated products taught by Morgante *et al.,*) having a size sufficient to contain with a probability of ninety-nine percent at least one copy of each of said pairs of sequence tags (ie., 10 bp). Although Morgante *et al.,* do not teach that at least one copy of said pairs of sequence tags is from each said restriction fragment of said genomic DNA as recited in claim 32, since that claim 32 is directed to a product and is not directed to a method of making a product, the patentability of claim 32 does not depend on how

the product recited in claim 32 is made. It is known that the patentability of a product does not depend on its method of production. If the claim is a product-by-process claim, it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding claim 33, since Morgante *et al.*, teach that different sequence tags have the same number of basepairs which are used to attach to the ends of genomic DNA restriction fragments (see Table IV in pages 76 and 77, SEQ ID NOs: 7-10), Morgante *et al.*, disclose that each sequence tag of each of said pairs (ie., SEQ ID NOs: 7-10) contains the same number of basepairs as recited in claim 33.

Therefore, Morgante *et al.*, teach the limitation recited by claims 28-33.

Response to Arguments

In page 7, second paragraph bridging to page 8, first paragraph of applicant's remarks, applicant argues that "the resulting adaptor-fragment-adaptor constructs would have to be greater than 20 nucleotides in length, and would typically be much longer, depending on the length of the fragment. Moreover, the adaptors are not ligated to each other, but to both ends of a DNA fragment".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, since Morgante *et al.*, teach ligated products with 10 bp adaptor sequences

on each end of the ligated products, Morgante *et al.*, disclose the oligoncleotide containing a ligated pair of sequence tags wherein a 10 bp adaptor sequences on one end of the ligated product is connected to another 10 bp adaptor sequences on another end of the ligated product by the genomic DNA restriction fragment. Second, the claims do not require that pair of sequence tags directly connects each other.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
March 11, 2005

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
3/15/05